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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/840,485 | 04/23/2001 | Rocky Barry Bigbie | AM100123 | 5730 |

25291 7590 06/21/2005

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| PORTNER, VIRGINIA ALLEN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/840,485 | BIGBIE ET AL. | |
| | Examiner | Art Unit | |
| | Ginny Portner | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *3,9,15-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8 and 10-14* is/are rejected.

7)☒ Claim(s) *1,2,5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



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## DETAILED ACTION

Claims 1-22 are pending; claims 3,9,15-22 stand withdrawn from consideration.

**1.** The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### Response to After Final Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action has been considered, the finality of that action is withdrawn and new grounds of rejection will be set forth below.

2. The Amendment of the Specification inserting the narrative that the "ATCC deposit" was made under the Budapest Treaty was entered but no Declaration of Deposit or Deposit Receipt showing that the deposit was made under the Budapest Treaty was submitted with the Amendment After Final and therefore inserts New Matter into the Specification.

**Please Note**: The examiner is rejoining Sarcocystis neurona inactivated cells and antibody inducing derived antigens from said cells in this action.

**Ochiai/Brouwer Rejoinder** The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP э 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined

process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. ∋ 103(b),≅ 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP ∋ 804.01.

***Rejections Withdrawn***

3. The rejection of claims 1-2, 4-8 and 10-14 under 35 USC 112, first paragraph (written description, Deposit requirement) is herein withdrawn, in light of the claims not being directed to a deposited strain of the composition under consideration.
4. Claim 1 rejected under 35 U.S.C. 112, second paragraph, for reciting the term "capable" is herein withdrawn in light of Applicant's prior traversal.
5. Claim 5 rejected under 35 U.S.C. 112, second paragraph, for reciting the term "optionally" is herein withdrawn in light of the scope of the claims is clear.
6. Claims 10 and 11 rejected under 35 USC 112, second paragraph for reciting term "about" is herein withdrawn in light of Applicant's prior traversal.
7. Claims 4, 6, 8 and 9 rejected under 35 USC 112, second paragraph for reciting the term "sufficient quantity", in light of new grounds of objection/rejection set forth below and the fact that claim 9 stands withdrawn from consideration.
8. Claim 5 rejected under 35 USC 112, second paragraph for the phrase "effective immunizing amount" in light of new grounds of objection/rejection set forth below .

***Rejections Maintained***

9. Claims 1-2, 4-8 and 10-14 are rejected under 35 USC 112, first paragraph (vaccine compositions), while being enabled for the inducing of S.neurona specific neutralizing antibodies

with inactivated whole cells and S.neurona 30 and 16 kDa derived antigens from merozoites, does not enable the use of any derived antigen, to include single proteins that comprise epitopes (definitions provided on pages 12 of the instant Specification) for induction of a protective immune response.The specification fails to teach how to formulate and use the claimed vaccines. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to infection or disease induction. The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity using any single antigen, or protein for treating infection, or preventing infection by S.neurona. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing infections caused by S.neurona protozoan. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced. The ability to reasonably predict the capacity of a single pathogen immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development ) is the identification of a protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single protein fails to elicit protective immunity even though a high level of serum antibody response is s induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

While the Specification teaches inactivated whole cells, and 30 and 16 kDa protein antigens that are able to induce neutralizing protozocidal antibodies, the specification fails to provide an adequate written description of other proteins or other derived antigens that can be used in the claimed vaccine compositions, the skilled artisan would be required to de novo locate, identify and characterize the claimed other proteins. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to other surface proteins with the claimed characteristics.

10. The rejection of claims 1-2, 4-8, as previously applied to claim 1, 2 and 4 under 35 U.S.C. 102(b) as being anticipated by Granstrom et al (1993) is maintained for reasons of record and as set forth below in a newly formatted rejection.

***New Grounds of Rejection/Objection***

***Specification***

11. The amendment filed After Final, on May 12, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "The deposit was made under the conditions mandated by 37 C.F.R. 1.808 and is being maintained pursuant to the Budapest Treaty". As a Declaration of Biological Deposit showing that the material was in fact deposited under the Budapest Treaty has not been made of record at any time during the prosecution of this Application; the amendment of the Specification inserts New Matter into the instant Specification. Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Objections***

12. Claims 1, 2 and 5 are objected to because of the following informalities:

13. Claim 1 recites the phrase "selected from the group consisting of" which introduces a Markush Group. A Markush group is a group of species of invention that share a common structure and biological function. As DNA and protein antigens do not share a common chemical structure or biological function, the Markush group set forth in claim 1 (and all claims dependent therefrom) is not proper. Additionally, the members of a Markush group should be separated one from the other with commas "," and not semi-colons ";". The correct format should be A, B,

C, D, E and F (see MPEP section 21873.05(h). Extraneous commas should be removed to prevent confusion as to what is actually a claimed species verses just descriptive narrative.

14. Claim 2 recites non-elected inventions and therefore does not set forth the invention under examination. Additionally, claim 2 recites terms which are separated by a semi-colon ";" which defines separate inventions. Claim 2 recites the phrase "inactivated Sarcocystis neurona cells" which are not limited to the merozoite form recited in claim 1, from which claim 2 depends, thus broadening the scope of claim 1; claim 2 is not further limiting of claim 1 as the inactivated cells need not be a merozoite inactivated Sarcocystis neurona cell.

*15.* Claim 5 also recites both a semicolon and commas. The semicolon appears to set forth an additional invention and should be removed to provide clarity to what is being claimed.

16. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 1, 4-8,10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

19. Claim 1 recites "a merozoite or tachyzoite antibody inducing antigen derived from said cells". The term cells refers back to all of the cells recited in the claim, for both recited antigens. The Sarcocytis neurona cells which are defined to be merozoite stage protozoan cells does not provide antecedent basis for the term "tachyzoite" . What antigen or cell serves as both a

merozoite and tachyzoite antigen simultaneously is not distinctly claimed. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

20. Claims 4,6 and 7 recite the limitation "**unit dose form**" in reference to a "component". The component may be an inactivated cell or an antibody inducing antigen derived from the cell. The terms "component" and "antigen" do not provide antecedent basis for the term "unit dose". There is insufficient antecedent basis for the term "unit dose form" in the claims from which claims 4, 6 and 7 depend. Claims 4, 6 and 7 should be amended to recite the phrase "further comprising" or a "wherein" statement that defines what the unit dose is and what "form" the composition is in. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed relative to the recited "unit dose form"

*21.* Additionally, a single antigen derived from a cell does not equal an inactivated cell. Claims 4, 6 and 7 recite the phrase "wherein said **active component** is present in sufficient quantity to provide at least $1 \times 10^4$ inactivated cells per unit dose form" or "at least $1 \times 10^6$ inactivated cells per unit dose form" and seeks to further limit claim 1 through further defining/limiting the term recited in the preamble of claim 1 "active component" . The "active component" is defined by the various members of the Markush Group set forth in claim 1, each

member serving as an active component, but it is unclear how each recited member of the Markush Group can act in a manner similar to at least 1 X $10^4$ inactivated cells. No definition has been provided as to what quantity of derived antigen must be present in the composition to equal what is encompassed by the phrase "at least 1 X $10^4$ inactivated cells" . Claims 4, 6 and 7 are confusing as the instant Specification does not provide a definition of what this quantity is relative the active components that are derived antigens of claim 1 when the antigen is other than inactivated whole cells.

*22.* Claim 5 recites the phrase "effective immunizing amount". What amount of the active component is present in the claimed composition based upon the fact that the composition is for any type of immunizing is unclear. The amount of active component needed to induce an antibody verses the amount to provide protection against infection would differ as a single antibody would not be effective in preventing infection by a plurality of protozoal cells that would cause disease. Claim 5 is directed to a vaccine which should induce protection, but the effective amount is not so claimed to be in agreement with the recited intended use of the preamble. The language recited in the body of the claim is not internally consistent with the preamble of the claim as the "amount" is effective for any type of immunizing and not so claimed as to require the amount to be a therapeutically effective amount to provide protection against infection.

23. Claim 8 depends from claims 2 and 1 and seeks to further limit the active component by functionally defining the "amount" that is present in the composition. The amount is functionally defined by referring to the "type of immune response induced, specifically "inducing serum neutralizing antibody response which is protozocidal". What amount of active

component would function in this manner is not distinctly claimed. The amount recited in claim 8 must induce a "serum neutralizing antibody that is protozocidal". The function of the antibody induced is a very specific type of antibody, but claim 8 is not drawn to an antibody but to an amount of active component that will produce this type of antibody. While the term merozoite evidences antecedent basis in claim 1 from which it indirectly depends, the term "merozoite" lacks antecedent basis in the other terms recited in the Markush group of claim 1 and 2, and what the amount of the active components is in the composition of claim 8, is not clearly set forth in claim 8. Each amount of the active components of claim 1 must induce a serum merozoite neutralizing antibody (binding) that is also protozocidal (killing); these amounts have not been defined in the instant Specification,.

24. Claims 10-14, directly or indirectly depend from claim 5 and require the optional adjuvant to be present in the claimed composition, in an amount that is "about 1% to 50% wt/wt" (claim 10), or "about 5% to 20% wt/wt" (claim 11). While one of skill in the art would clearly know how to formulate a composition based upon a wt/wt ratio once the weights in the composition are known. The weight of the adjuvant would readily be determined based upon the adjuvant selected, but what the second weight is, is not clearly pointed out in the claims. The second weight could be the based on the immunologically active component (the derived antigens or inactivated cells), the pharmaceutically acceptable carrier, or the combination of both, but the weights are not defined in the claims, so how much immunologically stimulating adjuvant is present in the composition is not clearly set forth in the claims. Does the second recitation of "wt" refer back to the active component or the carrier or the combination of both;

or an additional reagent? What component or components serve to define the second recited "wt" term of the claims?

***Claim Rejections - 35 USC § 102***

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

26. Claims 1-2, 4-8, as previously applied to claim 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Granstrom et al (1993) as evidenced by US Pat. 5,554,371 (detailed description paragraph 31).

Granstrom et al disclose the instantly claimed invention directed to a composition that comprises active components of Sarcocystis neurona merozoites, wherein the compositions comprised:

**Instant claim 1-2, 4-8**: inactivated Sarcocystis neurona merozoites cells were produced by solubilization (see page 88, col. 1, paragraph 3, "1 X $10^6$ purified merozoites") and from the inactivated cells Sarcocystis neurona merozoite derived antigens were obtained when they (see Figure 1 and Table 1, page 89, instant claims 6-7) were combined with an acceptable carrier (SDS-PAGE, an acceptable carrier, as evidenced by US Pat 5554371 which shows the SDSgel as a carrier used in formulation of a vaccine composition) .

The merozoite active component antigens immunoreacted with antibodies (see Table 1, immunoblot analysis), the antibodies having been produced in response to an active component of Sarcocystis neurona cells (see antisera prepared in rabbits, page 88, col. 2, middle of second

paragraph). Clearly the compositions of Granstrom et al comprised immunogenic merozoite derived antigens of Sarcocystis neurona inactivated cells, the antibodies being induced by the same or equivalent merozoite active agents of the instant claims. By all comparable data, and though not mentioned in the Granstrom et al reference, the active component containing compositions appear to be the same or equivalent compositions now claimed and therefore would inherently induce a serum neutralizing antibody.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

27. Claims 1-2, 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Liang et al (1998).

Liang et al disclose the instantly claimed invention directed to compositions of inactivated Sarcocystis neurona cells, wherein the cells of Liang et al were inactivated by heating in a boiling bath (see page 1834, col. 2, paragraph 6).

Additionally $8 \times 10^7$ merozoites were inactivated cells by treatment with lysis buffer (pH 7.6) (see page 1835, col. 1, paragraph 3), or by extraction by trypsin digestion (see page 1835, col. 2, paragraph 2).

Antigens derived from the inactivated cells that evidenced relative molecular weights of antigens of 30, 16, 14 and 11 kDa (see page 1835, col. 2, paragraph 4 and page 1836, Figure 3) were visualized and found to immunoreact with neutralizing antibodies (see Figure 2, and col. 1, paragraph 1, page 1836).

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

28. Claims 1-2, 5 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Mansfield et al (US Pat. 6,489,148, effective filing date September 18, 1998).

Mansfield et al disclose compositions that comprise inactivated Sarcocystis neurona merozoite (see col. 6, line 8) derived antigens of 30 and 16 kDa (see claims 2 and 11, col. 9 and 10), which are referred to as "immunodominant proteins (see col. 7, line 63) were combined in a

gel and contacted with buffered saline containing tween and tris (see col. 6, lines 8-19 and lines 63-67), both carriers for the derived antigens Mansfield et al anticipates the instantly claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

29. Claims 1-2, 4-8, 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Dubey et al (1999).

Dubey et al disclose several compositions of inactivated S.neurona cells and derived antigens therefrom,:

a. (instant claims 1-2, 4) Inactivated cells in tissue fixed with 10% buffered neutral formalin (see page 501, col. 1, paragraph 1). The active component containing inactivated cells were immunoreactive with antibodies (see Figure 3, frame C, page 504);

b. (instant claims 1-2, 4-8) Merozoite inactivated cells was produced using $1x10^7$ cells per 100 microliters in 0.9% NaCl solution, wherein they were inactivated by being

solubilized (see page 501, col. 1, paragraph 5);

c. (instant claims 1-2, 4-8, 10-14) a composition of merozoite inactivated cells 1.7 $x10^7$ cells (frozen with dry ice and 95% ethanol at –70°C) were mixed with a immunostimulating adjuvants consisting of a surfactant and oil (ImmuMax-SR,Zonagen Inc, see page 501, col. 1, paragraph 4, "third immunization");

1. (instant claims 1-2, 4-5, 8) derived antigens were partially purified through gel electrophoresis and visualized with antibodies (Figure 4, page 504, which shows a plurality of S. neurona antigens immunoreactive with antibodies induced by vaccination, the antigens being of about 12.4, 14.3, 23.8 and 31.5 kDa, as well as 16 kDa (see page 503, col. 2, paragraph 3)).

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

***Conclusion***

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

31. Bubey et al (1999) is cited to show S.neurona derived merozoite antigens of 13, 11.4, 11 and 10.5 kDa which are considered to be diagnostic for S.neurona infection as they immunoreact with antibodies induced during S.neurona infection (see page 60, section 2., paragraph 2).
32. Liang et al (1997) disclose the instantly claimed invention directed to compositions of inactivated Sarcosystis neurona cells, wherein the cells of Liang et al were inactivated by heating in a boiling bath (see page 62, col. 1, paragraph 2). Additionally merozoite derived antigens of 100, 30 and 19 kD (see page 65, col. 1, paragraphs 3-4) which were separated and visualized in PAGE carrier and immunoblot (see page 62, Figure 1, B and page 63, Fig. 2 and 3) and the purified antigens combined with double distilled water (see page 62, col. 2, paragraph 1, last two sentences) . One of the proteins was used to induce production of antibodies in a mammalian host animal, thus showing the N-terminal portion to be a merozoite active component derived which is immunogenic (see page 65, col. 1, paragraph 3).
33. Mansfield et al (US Pat. 6,153,394) is cited to show Sarcocystis neurona 16 and 30 kDa antigens.
34. Murphy et al (1999) is cited to show chemical excystation of Sarcosystis by three different methods that utilize trypsin (see page 980, col. 2, paragraph 2, top of paragraph).
35. Rossano et al (January 2000) is cited to show species specific antigens of 16 and 30 kDa in the detection of infection caused by Sarcocystis neurona.
36. Animal Pharm March 2001 (abstract) is cited to show the issuance of a conditional license to For Dodge for an equine protozoal myeloenchephalitis vaccine (filed February 2001).
37. Wyeth Medical Device Company (abstract) is cited to show a conditional license for a vaccine to help prevent equine protozoal myeloencephalitis.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
June 12, 2005

L. F. Smith
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